42.39.106 REGISTERED CARDHOLDER APPLICATION PROCESS (1) An applicant must be a resident of the State of Montana.

- (2) All applications must be completed on forms provided by the department.
- (3) A complete application must include the required fee, statements, and forms required in the application packet to be accepted and processed by the department. Any documents submitted electronically must be uploaded in a format that the department is able to access and view.
- (4) The registry identification card expires one year from the date of issuance unless the physician statement provides a written certification for a shorter period of time.
- (5) A physician statement must be dated within 60 days of the application date. The department shall deny an application submitted with a physician statement dated more than 60 days from the application date.
- (6) Any denial under this part is subject to a contested case hearing before the department's Office of Dispute Resolution, as provided for under ARM 42.2.621.
- (7) A registered cardholder who submits a renewal application less than 30 days prior to the registry identification card's expiration date assumes the risk and possibility of the card expiring until the department processes and approves the renewal application.
- (8) A custodial parent or legal guardian may submit an application for a minor under 16-12-508, MCA.

AUTH: 16-12-112, MCA

IMP: 16-12-112, 16-12-503, 16-12-508, 16-12-509, MCA

42.39.107 LICENSE AND ENDORSEMENT APPLICATION PROCESS

- (1) An applicant must be a resident of the State of Montana.
- (2) All applications must be completed on forms provided by the department.
- (3) Licenses expire one year from the date of issuance, except for marijuana transporter licenses which expire two years from the date of issuance.
- (4) Renewal applications must be submitted at least 60 days prior to the expiration date of the license.
- (5) The department will approve or deny an a new application within 120 days of receiving a complete application and will approve or deny a renewal application within 60 days of receiving a complete application. An application is considered complete when the applicant or licensee, as applicable, has provided all statements, forms, diagrams, operation plans, and other applicable documents required in the application and has paid the nonrefundable processing fee pursuant to [MAR Notice No. 42-1033, NEW RULE I(2)] and has paid the remaining balance of the license fee upon notification by the department of its pending approval.
- (6) If a renewal application is received less than 60 days prior to license expiration, the department will process the application, but the licensee assumes the risk and possibility of having to suspend operations until the department processes and approves the renewal application.
- (7) Prior to approving an application, the department may contact any applicant or individual listed on the application and request additional supporting documentation or information.
- (8) Prior to issuing a license or endorsement, the department will inspect the proposed premises to determine if the applicant complies with the marijuana laws.
 - (9) If a licensee fails to submit a renewal application prior to the license or

endorsement expiration date, the licensee may not continue to operate.

- (10) The department will not consider a renewal applications received after the license or endorsement expiration date, in which case the license will lapse.
- (11) The department will not amend or extend a license's expiration date unless the licensee can demonstrate that its failure to timely submit a renewal application was due to circumstances beyond its control.
- (12) A licensee may not operate until on or after the effective date of the license.
- (13) Any denial under these rules is subject to a contested case hearing before the department's Office of Dispute Resolution, as provided for under ARM 42.2.621.

AUTH: 16-12-112, MCA

IMP: 16-12-112, 16-12-201, 16-12-203, 16-12-503, MCA

- 42.39.117 DENIAL OF REGISTRY IDENTIFICATION CARD APPLICATION OR REVOCATION OF REGISTRY IDENTIFICATION CARD (1) The department, after written notice to the applicant or registered cardholder, may deny or revoke an application or registry identification card if:
 - (a) the applicant did not provide the information required in the application;
- (b) the department determines the information provided in the application was inaccurate, misleading, or falsified;
 - (c) the applicant did not submit the required fee with the application;
- (d) the applicant or registered cardholder does not have, or no longer has, a debilitating medical condition as defined in 16-12-102, MCA;
 - (e) the applicant is not a resident of the State of Montana;
- (f) the applicant is in the custody of or under supervision of the Department of Corrections or youth court;
- (g) the applicant or registered cardholder is found to be in violation of 16-12-523, MCA;
- (h) the applicant or registered cardholder did not report changes to the department in accordance with ARM 42.39.311;
- (i) the registry identification card has been found to be altered or manipulated in any way; or
- (j) the cardholder violates the daily possession or purchase limitations contained in 16-12-515, MCA; or
- (jk) the registered cardholder is found to be in violation of any provision under Title 16, chapter 12, part 5, MCA.
- (2) Any denial or revocation under this part is subject to a contested case hearing before the department's Office of Dispute Resolution, as provided under ARM 42.2.621.

AUTH: 16-12-112, MCA

IMP: 16-12-108, 16-12-112, 16-12-203, 16-12-503, 16-12-515, 45-9-203, 61-11-101, MCA

42.39.118 ALLOWABLE AMOUNTS (1) A registered cardholder may submit a petition for an increase in the monthly purchase limits defined in 16-12-505, MCA, on a form approved by the department and submitted through the licensing system.

- (a) The department may take prior sales history and other factors deemed relevant into account when evaluating a petition for an increase in sales limits.
- (b) The department may approve increases to the monthly purchase limits up to a maximum of 8 ounces of usable marijuana or the equivalent in marijuana products as described in (2).
- (2) Usable marijuana may be in the form of flower or marijuana products. The following conversion shall be used to determine the allowable amounts of non-flower marijuana:
 - (a) 1 ounce of marijuana flower is equal to:
 - (i) 800 mg of THC in marijuana-infused products including edibles; or
 - (ii) 8 grams or 8 mL of THC in marijuana concentrate.
- (b) A registered cardholder may purchase or possess any combination of marijuana flower or marijuana products if the total calculated conversion is equal to or less than the legal purchase or possession amount.

IMP: 16-12-112, 16-12-207, 16-12-210, 16-12-301, 16-12-503, 16-12-515,

MCA

42.39.202 SEED-TO-SALE TRACKING SYSTEM USER REQUIREMENTS

- (1) A licensee must have a department seed-to-sale tracking system account activated and functional prior to operating or exercising any privileges of the license and must maintain an active account while licensed.
- (2) Additional licensees or licensee employees may be authorized to obtain seed-to-sale tracking system user accounts.
- (3) To obtain and maintain a seed-to-sale tracking system user account, a licensee or licensee employee must successfully complete all required department seed-to-sale tracking system training.
- (4) An individual entering data into the seed-to-sale tracking system may only use that individual's seed-to-sale tracking system account.
 - (5) A licensee must ensure:
- (a) all seed-to-sale tracking system users are up to date on seed-to-sale tracking system user training requirements; and
- (b) any data that is entered into the seed-to-sale tracking system in error is corrected.
- (6) A licensee and any designated seed-to-sale tracking system user must enter data into the seed-to-sale tracking system that accounts for all seed-to-sale tracking activities.
- (7) A licensee is accountable for all actions seed-to-sale tracking system users take while logged into the seed-to-sale tracking system.
- (8) A licensee is responsible for the accuracy of all information entered into the seed-to-sale tracking system.
- (9) Nothing in this rule prohibits a licensee from using secondary separate software applications to collect information to be used by the business, including secondary inventory tracking or point-of-sale systems.
- (10) If a licensee uses a separate software application that links to the seed-to-sale tracking system it must get approval from the seed-to-sale tracking system vendor contracting with the department and the software application must:
- (a) accurately transfer all relevant inventory tracking system data to and from the seed-to-sale tracking system; and

- (b) preserve original seed-to-sale tracking system data when transferred to and from a secondary application.
- (11) If a licensee loses access to the seed-to-sale tracking system <u>due to a power outage or other connectivity issue</u>, the licensee must keep and maintain comprehensive records detailing all seed-to-sale inventory activities that were conducted during the loss of access.
- (12) Once access is restored, all seed-to-sale tracking activities that occurred during the loss of access must be entered into the seed-to-sale tracking system.
- (13) A licensee must document when access to the seed-to-sale tracking system was lost and when it was restored.
- (14) All compliance notifications from the seed-to-sale tracking system must be resolved in a timely fashion.

IMP: 16-12-105, 16-12-112, 16-12-203, MCA

- 42.39.203 SEED-TO-SALE TRACKING AND RECONCILIATION (1) A licensee must use the department's seed-to-sale tracking system as the primary inventory and record keeping system.
- (2) Each individual marijuana plant that reaches a height of twelve inches must be issued a unique identification number in the seed-to-sale tracking system, which follows the plant through all phases of production and final sale to a registered cardholder.
- (3) All marijuana items, test batches, harvest lots, and process lots must be issued a unique identification number in the seed-to-sale tracking system.
 - (4) Unique identification numbers cannot be reused.
- (5) Each marijuana plant, marijuana item, test batch, harvest lot, and process lot that has been issued a unique identification number must have a physical tag placed on it with the unique identification number.
- (6) The tag must be legible and placed in a position that can be clearly read and must be kept free from dirt and debris.
- (7) Licensees must use unique identification tags purchased from the seed-to-sale tracking system vendor.
- (8) All on-premises and in-transit marijuana item inventories must be reconciled in the seed-to-sale tracking system at the close of business each day.
- (9) For each marijuana sale or transfer to a registered cardholder, the licensee or its employee must verify the registered cardholder's eligibility and daily and monthly purchase limits and record in the seed-to-sale tracking system at the time of sale or transfer:
 - (a) the quantity of each item sold or transferred to a registered cardholder;
 - (b) the price before tax; and
 - (c) the date of the sale or transfer to a customer.
 - (10) Licensees must record in the seed-to-sale tracking system:
 - (a) wet weight of all harvested marijuana plants immediately after harvest;
 - (b) information for marijuana items by unit count;
 - (c) weight per unit of a product;
- (d) weight and disposal of post-harvest waste materials, per the requirements described in ARM 42.39.310;
 - (e) theft or loss of marijuana items; and
 - (f) other information as may be required by the department.

- (11) These requirements do not apply to marijuana items held by a laboratory licensee that are undergoing analytical testing, so long as the marijuana items do not leave the laboratory's licensed premises and are reconciled on the same day that the quality assurance testing concludes.
- (12) All samples taken for quality assurance testing must be recorded in the seed-to-sale tracking system.
- (13) Licensed testing laboratories must record all testing results in the seed-to-sale tracking system.

IMP: 16-12-105, 16-12-108, 16-12-112, 16-12-203, 16-12-209, 16-12-210, 16-12-515, MCA

- 42.39.310 WASTE MANAGEMENT (1) A licensee must store, manage, and dispose of solid and liquid waste generated during marijuana production and processing in accordance with applicable state and local laws and regulations.
- (2) A licensee must store marijuana waste in a secured waste receptacle in the possession of and under the control of the licensee.
 - (3) Waste that must be rendered unusable prior to disposal includes:
- (a) marijuana plant waste, including roots, stalks, leaves, and stems that have not been processed with solvent;
 - (b) waste solvents used in the marijuana process;
- (c) spent solvents, laboratory waste, and excess marijuana from any quality assurance testing; and
 - (d) marijuana items that ultimately fail to meet testing requirements.
- (4) The allowable method to render a marijuana item unusable is by grinding (for solids) and incorporating or absorbing (for liquids) the marijuana item with other ground materials so the resulting mixture is undesirable, unrecognizable, unfit for human use, and incapable of growth or germination. For whole marijuana plants, the resulting mixture must be at least 50 percent nonmarijuana waste by volume.
- (5) For purposes of this rule, "use" includes, but is not limited to, ingestion, inhalation, topical application, processing, or remediation.
 - (6) Nonhazardous marijuana waste shall be disposed of as follows:

Marijuana Item	Destruction Method	Disposal Method
Marijuana plants	Mix with yard debris, wood chips,	Compost or
	sawdust, soil, manure, vegetable-	anaerobic
	based grease or oils, other wastes	digester, if
		available, off site
Usable marijuana	Mix with yard debris, wood chips,	Landfill, transfer
	sawdust, soil, manure, vegetable-	station, or
	based grease or oils, other wastes	incinerator, if
		composing not
		available or
		feasible
Liquid concentrate,	Absorb in cat litter, slack lime, soil, or	Landfill, transfer
extracts, or infused	similar substance	station, or
products		incinerator

Solid concentrate,	Mix with soil, slack lime, garbage, or	Landfill, transfer
extracts, or infused	similar substance	station, or
products		incinerator

- (7) Marijuana testing laboratories, marijuana manufacturers, and other licensees that generate hazardous waste shall follow all applicable rules and regulations for the disposal of hazardous waste, including ARM 17.53.105 and 17.53.113. Licensees need to contact the Department of Environmental Quality Hazardous Waste Program for assistance.
- (8) A licensee must maintain accurate and comprehensive records regarding waste material in the seed-to-sale tracking system that accounts for, reconciles, and evidences all waste activity related to the disposal of marijuana to include:
 - (a) what was disposed;
 - (b) quantity by weight or volume;
 - (c) date disposed; and
 - (d) reason for the disposal.
- (9) A licensee must provide a minimum of 72 hours' notice in the seed-to-sale tracking system prior to rendering the marijuana item unusable and disposing of it.

IMP: 16-12-103, 16-12-105, 16-12-112, 16-12-203, 16-12-210, MCA

- 42.39.311 REPORTING REQUIREMENTS (1) A registered cardholder must notify the department within ten days of any changes in the following:
 - (a) cardholder's name or address;
 - (b) referral physician; or
 - (c) change in the status of the cardholder's debilitating medical condition.
- (2) A registered cardholder must report to the department within ten calendar days any lost or stolen registry identification card.
- (3) A licensee must notify the department within ten days of any changes in the following:
- (a) anyone identified as an applicant or controlling beneficial owner or anyone with a financial interest in the license;
 - (b) <u>its standard</u> operating hours;
 - (c) temporary closure of longer than 30 days; and
 - (d) permanent closure of the business.
- (4) A licensee who wishes to change the location of a licensed premises must submit a completed application for the new premises including all required forms, documents, and fees.
- (5) A licensee who intends to make any material or substantial changes to the licensed premises must <u>submit notify the department of</u> the <u>proposed changes</u>. to the department for approval prior to making any such changes. Material or substantial changes include:
- (a) any increase or decrease in the total physical size or capacity of the licensed premises;
 - (b) alterations to public ingress or egress of limited access areas;
 - (c) any changes to the security plan.
- (6) A licensee must notify the department as soon as reasonably practical but in no case more than 24 hours following the theft of marijuana items or money from the licensed premises.

AUTH: 16-12-112, 16-12-533, MCA

IMP: 16-12-112, 16-12-202, 16-12-203, 16-12-503, 16-12-508, 16-12-533, MCA

42.39.312 MARIJUANA ITEM RECALLS (1) For purposes of this rule, the following definitions apply:

- (a) "affected licensee" means a licensee whose marijuana or marijuana products are subject to a recall. More than one licensee may be an affected licensee in a recall;
- (b) "affected product" means marijuana or a marijuana product subject to a recall.
- (2) A recall is required when marijuana or marijuana products pose a risk to public health and safety. A recall shall be based on evidence that marijuana or a marijuana product is contaminated or otherwise unfit for human use, consumption, or application.
- (3) A licensee must develop a recall plan that establishes the procedures the licensee will follow in the event of a recall of its product or products. A recall plan must, at a minimum:
- (a) designate a member of the licensee's staff who serves as the licensee's recall coordinator;
- (b) establish procedures for identifying and isolating product to prevent or minimize its distribution to customers;
 - (c) establish procedures to retrieve and destroy product; and
- (d) establish a communications plan to notify those affected by the recall, including:
- (i) how the affected licensee will notify registered cardholders and other licensees in possession of affected product; and
- (ii) the use of a press release and other appropriate notifications to ensure customers are notified of the recall and affected product information.
- (4) If the department or the Department of Public Health and Human Services determines that a recall is required, an affected licensee shall:
- (a) immediately notify registered cardholders and other licensees that received the affected product;
- (b) immediately issue a press release or other appropriate public notification to inform customers of the recall and identifying information about the affected product recalled;
- (c) provide the department with a copy of the press release or other appropriate public notification in (4)(b);
- (d) post on its website, if applicable, information about the recall and the affected product; and
- (e) perform a causation analysis to determine the issue or issues leading to the recall and provide to the department a corrective action report and preventative action report, as both are defined by the Department of Public Health and Human Services, which details how the affected licensee plans to correct and prevent future recalls
- (5) An affected licensee must coordinate with the department for destruction of the affected product and allow the department to oversee the destruction.
- (6) An affected licensee must track the total amount of affected product and the amount of affected product returned to the affected licensee as part of the recall

effort. The affected licensee must periodically report to the department on the progress of the recall efforts.

- (7) If an affected licensee determines that a recall is required, it must immediately notify the department. The affected licensee must then follow the procedures established in (4) through (6).
- (8) If the department determines that a recall is successful, and the risk to public health and safety is no longer present, the department shall notify the affected licensee and close the recall.
- (9) The department shall maintain a marijuana recall page on its website of all current recalls.

AUTH: 16-12-112, MCA

IMP: 16-12-105, 16-12-112, 16-12-209, MCA